

REMARKS

Claims 1-52 were pending. Claims 1, 4-8, 17, 22, 39-40, 42-46, and 51 are amended. Claims 41, 47-50, and 52 are cancelled without prejudice in order to facilitate prosecution. New claims 53-83 are added. No new matter has been added. The applicant requests reconsideration in light of the following remarks.

1. Information Disclosure Statement

The applicant thanks the Examiner for returning the initialed Form 1449 copies for the Information Disclosure Statements filed on March 11, 2003 and May 15, 2003, and acknowledges that the URL given for the Umpire Screen jpeg file was incorrect. A Supplemental Information Disclosure Statement providing the correct URL, as well as a number of additional references, is being submitted with this Reply.

2. Objections to the Drawings

Figures 1, 2 and 4 were objected to. Corrected versions of Figures 1, 2 and 4 are submitted, along with a marked up copy of each of these drawings showing the changes being made. Processors 117 and 137, and memories 112 and 132 have been added to Figure 1 as requested, along with text labels identifying the respective computer systems, processors and memories. The specification has been amended to refer to the processors and memories by their respective reference numbers. In Figure 2, reference number 200 has been moved as requested, and “subsystem” has been added to the text for items 200 and 220, also as requested. The text label for database 270 has been changed to “Experiment DB” consistent with the accompanying description in the specification, as will be discussed below. In Figure 4, a START symbol has been added as requested. The applicant believes that these changes address all of the grounds for objection and requests that the objections be withdrawn.

3. Objections to the Specification

The specification is objected to for a number of informalities. The specification has been amended as requested to replace “22” with “22 on page 11, line 7, “210” with “220” on page 15, line 11, and “130” with “150” on page 18, line 18.

The Office action suggests that the term “Experiment” should be replaced with “results” in the context of Experiment database 270 to match Figure 2. However, the applicant respectfully points out that while database 270 is used to store experimental results, the term “Experiment database” was selected because the database can be used to store other experimental information in addition to results – for example, data relating to the experiment design (*e.g.*, library design, composition or processing conditions, and analytical or screening methods) in addition to measured or calculated properties reflecting experimental results. *See, e.g.*, page 20 lines 23-27. The applicant therefore respectfully submits that “Experiment database” properly reflects the scope of information stored in database 270, and has proposed a corresponding correction to Figure 2, as discussed above. Consistent with this, the specification has been amended to replace “Experimental” with “Experiment” at page 20, line 33.

4. Rejections under Section 101

Claims 1 and 39 are rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter, because the claims are allegedly directed to abstract ideas and their manipulation. The Office action suggests that these claims would be statutory if they were amended to recite computer-implemented methods.

Claim 1 is directed to a method for carrying out a set of experiments. As amended, the claim recites a method that broadly includes:

- i) providing a computer-implemented experiment design tool for generating an experiment design defining a set of experiments;
- ii) receiving a user input that includes a first experiment design generated by the experiment design tool;
- iii) preparing a library of materials based on the first experiment design (more specifically, “corresponding to [a] first experiment matrix” defined in the first experiment design);
- iv) applying a set of process conditions specified in the first experiment design to the members of the library of materials to transform at least one starting material into at least one product;

- v) applying a screening method specified in the first experiment design to the members of the library of materials to generate experimental results; and
- vi) providing electronic data describing the experimental results to the remote user.

As the applicant's specification explains in more detail, the claimed method is useful in the field of experimental research, and provides useful, concrete, and tangible results in the performance of a set of experiments designed by a user, and the communication to that user of results obtained from those experiments. That is, as is explained in more detail in the applicant's specification, the claimed invention permits a scientist to design a set of experiments, and to submit the experiment design to a remote laboratory for execution using high-throughput technologies. Experimental results are then returned to the scientist. *See, e.g., Specification at page 7, lines 11-14; page 12, lines 6-12.*

The applicant submits that in this context, many of the "abstract ideas" identified in the Office action are clearly embodied as electronic data generated by the computer-implemented experiment design tool. Thus, the claim provides that the experiment designs generated by the computer-implemented design tool include "electronic data defining an experiment matrix having a plurality of matrix elements, a set of one or more starting materials assigned to the matrix elements and a set of one or more process conditions to be applied to the matrix elements", and also include "electronic data defining a screening method to be applied to generate experimental results", clearly indicating that the claimed experiment designs are electronic data generated using a computer-implemented tool, and that the experiment matrix, matrix elements, and process conditions noted in the Office action are, at least initially, electronic data generated as a part of the experiment design. Likewise, the final step of the method, in which the experimental results are provided to the user, has been amended to reflect that the results are provided as electronic data.

However, the applicant submits that while all of the steps can be implemented in a computer or collection of computers, as reflected in some of the dependent claims, the third, fourth and fifth steps expressly require the manipulation of concrete, tangible things. As noted above, these steps require the preparation of a library of materials that

corresponds to the experiment matrix of the input experiment design, the application of the process conditions specified in that input design to the library members to transform starting materials to products, and the application of the specified screening method to the library members to generate experimental results. As such, these steps require the actual preparation of a library (or collection) of materials – that is, chemical compounds or mixtures such as chemical reagents, substrates, catalysts, stabilizers, additives, solvents, monomers, resins, polymers, supports, zeolites, molecular sieves, ligands, metal precursors, metal salts, metal oxides, metal complexes and the like (*see specification at page 8, lines 20-24*), the exposure of these materials to physical process conditions, such as temperature, pressure, mixing rate or the like (*see specification at page 10, lines 5-7*) to cause the library materials to undergo chemical or physical transformations, such as the formation or cleavage of chemical bonds or the formation of mixtures or alloys (*see specification at page 9, lines 8-34*), and the subsequent performance of analytical screening techniques, such as infrared thermography, chromatography, capillary electrophoresis, or mass spectrometry (*see specification at page 10, lines 11-16*) on the transformed materials. The applicant submits that these steps require the manipulation of actual materials, and not merely of abstract ideas as the Office action suggests. The applicant therefore submits that the claim is statutory and requests that the rejection under Section 101 be withdrawn.

Claim 39 has been amended as suggested to recite a “*computer-implemented* method for obtaining experimental results for a set of experiments”. The applicant submits that the amended claim is clearly directed to statutory subject matter and requests that the Section 101 rejection be withdrawn.

5. Rejections under Section 102

Claims 1-3, 9-21, 24, 26-27, 29, 31-45 and 47-52 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,329,139 (“Nova”). The applicant respectfully disagrees.

a. Claims 1-3, 9-21, 24, 26-27, 29, and 31-38

Claim 1 is directed to a method for performing a set of experiments that is particularly suited to contract research, and in particular to implementations in which a

research laboratory receives experiment designs from external customers, executes those experiment designs within the research laboratory organization to produce experimental results, and then provides those results to the customers outside of the research laboratory organization. *See Specification at page 7, lines 11-14; page 8, lines 13-17.* To that end, claim 1 is directed to a method in which a computer-implemented design tool is provided to a remote user at a first location. The computer-implemented design tool enables the user to generate an experiment design that includes electronic data that defines an experiment matrix having a plurality of matrix elements, a set of starting materials assigned to the matrix elements, and a set of process conditions to be applied to the matrix elements, such that a plurality of the matrix elements are defined by a unique combination of starting materials and/or processing conditions. The experiment design also includes electronic data defining a screening method to be applied to the experiment matrix to generate experimental results.

According to the claimed method, a user input is received at a second location that is remote from the first location. The user input includes an experiment design generated by the experiment design tool that defines an experiment matrix and a screening method. A library of materials is prepared at the second location according to the received experiment design, and the process conditions specified in the received experiment design are applied to the members of the prepared library of materials to transform at least one of the starting materials into at least one product. The screening method defined in the received experiment design is then applied to the members of the prepared library of materials at the second location to generate experimental results. Finally, the experimental results are provided to the remote user at the first location in the form of electronic data describing the results. Nova fails to disclose at least the claimed generation and execution of experiment designs, and design and execution of experiments at different locations.

Nova discloses an “automatic sorting system for matrices with memories”, in which “matrices-with-memories” serve as the platform on which manipulations relating to drug discovery protocols are performed or as the repository in which information relating to such manipulations is stored. *See Nova, Title; Abstract.* According to Nova, matrices-with-memories are “[c]ombinations of matrix materials with programmable data

storage or recording devices or other memory means". *Id.* at column 4, lines 59-60. These "matrix materials" are solid supports, such as particles, test tubes, or microtiter plates, formed from materials such as glasses, silicates, and polymers such as celluloses, polystyrenes, polysaccharides, and the like. *Id.* at column 6, line 61-column 7, line 5. Nova explains that molecules or biological particles, such as antigens, antibodies, proteins, phages and cells, are associated with the matrix materials – for example, by synthesizing the molecule on the matrix material support – and the memory associated with the matrix material is used to electromagnetically "tag" the molecule or particle by programming, imprinting or encoding the memory with identifying information. *Id.* at column 5, lines 31-40. The matrices-with-memories can then be used to track the associated molecule or biological particle in subsequent analyses or assays. *Id.* at column 6, lines 23-51; column 14, lines 36-41.

Nova does disclose the use of computer software in the organization, planning and design of chemical experiments using these matrices-with-memories (*see, e.g.,* column 96, lines 4-9), but it does not disclose, or even suggest, the use of such software to enable a remote user to generate an experiment design at one location, and the execution of such an experiment design by a research laboratory at a second, different location as claim 1 requires. To support its conclusion to the contrary, the Office action seems to cite column 5, lines 31-40 and column 95, lines 38-48 of Nova (*see* Office action at page 7, lines 13-16). But these passages disclose that molecules or particles associated with matrices-with-memories can be tagged by programming the associated memory or imprinting or encoding the matrix itself (column 5, lines 31-40) and a manual sorting system that includes devices and software for reading from and writing to matrices with memories, including for assisting the user in identifying a particular matrix-with-memory and the destination to which the matrix-with-memory is to be transferred (column 95, lines 38-48). The applicant respectfully submits that nothing in the cited passage discloses the provision of experiment design software to a user at a first location and the receipt and execution at a second location of an experiment design generated using such software.

Nor does Nova disclose experiment design software that generates experiment designs as recited in claim 1. For example, claim 1 recites that the computer-

implemented experiment design tool generates an experiment design that includes “electronic data defining a screening method to be applied to generate experimental results”. But while Nova does disclose the analysis of its matrices-with-memories using various assays or screening techniques (*see column 13, line 47-column 14, line 5 (cited in Office action)*), nowhere does it disclose, or even suggest, that electronic data specifying a particular assay or screen should be included in an experiment design generated using its disclosed software.

Because it fails to disclose at least these limitations of claim 1, Nova cannot anticipate that claim, or dependent claims 2, 3, 9-21, 24, 26-27, and 31-38, all of which depend directly or indirectly from claim 1 and therefore include all of the limitations of that claim. The rejection under 35 U.S.C. § 102(e) as to these claims should therefore be withdrawn.

Claims 17-21 are allowable over Nova for at least the following additional reasons. Claim 17 is a dependent claim based on claim 1, and recites that the method comprises the additional steps of evaluating the first experiment design to generate an experimental plan describing a proposed execution of the set of experiments; providing the experimental plan to the remote user; and receiving an input from the user in response to the experimental plan. According to the claim, the steps of preparing the library of materials, the applying the process conditions, applying the screening method, and providing the experimental results are only performed when the user approves of the experimental plan. Claims 18-21 depend directly or indirectly from claim 17 and provide additional details regarding the evaluation by which the experimental plan is generated.

Even assuming Nova discloses the generation and use of an experiment design as recited in claim 1 (which it does not, as discussed above), the reference does not disclose, or even suggest, the step of evaluating such an experiment design to generate an experimental plan, the provision of such an experimental plan to the user, or the conditioning of the execution of the experiment upon the approval of such an experimental plan by the user. For at least these additional reasons, Nova fails to anticipate claims 17-21, which should therefore be allowed.

b. Claims 39-40

Claim 39 is an independent claim directed to a computer-implemented method for obtaining experimental results for a set of experiments. As amended, the method includes the steps of generating an experiment design defining a set of experiments at a first location, communicating the experiment design to a laboratory at a second, different, location for execution, and receiving at the first location experimental results obtained by execution of the set of experiments at the laboratory. As in claim 1, the experiment design includes an experiment matrix, one or more starting materials assigned to the matrix elements, and one or more process conditions to be applied to the matrix elements, such that each of a plurality of matrix elements being defined by a unique combination of starting materials and/or process conditions. The claim also specifies that the experiment design also defines a screening method to be applied to generate the experimental results.

Amended claim 39 thus includes limitations analogous to those discussed above in the context of claim 1 (albeit from the perspective of the user, as opposed to the laboratory as in claim 1); accordingly, claim 39 and dependent claim 40 are allowable for at least the reasons discussed above in the context of that claim.

c. Claims 41-45

Claim 41 has been cancelled without prejudice, rendering the rejection moot as to that claim. Claims 42-45 are dependent claims and have been amended to depend directly from claim 39. Accordingly, claims 42-45 include all of the limitations of claim 39 and are allowable over Nova for at least the same reasons discussed above.

d. Claims 47-52

Claim 51 is an independent claim directed to a computer-readable storage medium tangibly embodying a research system program comprising instructions operable to cause a programmable processor to perform a sequence of steps directly analogous to the method steps recited in claim 1. Accordingly, the applicant submits that claim 51 is allowable over Nova for at least the reasons discussed above in the context of claim 1.

Claims 47-50 and 52 have been cancelled without prejudice, rendering the rejection moot as to those claims.

6. Rejections under Section 103

Claims 4-8, 22-23, 25, 28, 30 and 46 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nova in view of U.S. Patent No. 5,569,799 (“Chen”), U.S. Patent No. 5,969,121 (“Allen”), U.S. Patent No. 5,849,578 (“Falb”), U.S. Patent No. 4,710,864 (“Li”), and William J. Lennon *et al.*, “Using a Distributed Mini-computer Network to Automate a Biochemical Laboratory” (publication information unknown) (“Lennon”). The applicant respectfully disagrees.

a. Claims 4-8

Claims 4-8 are dependent claims based, as amended, on claim 1. In addition to the limitations of their base claim, these claims add the limitations that the first experiment matrix includes at least 50 (claim 4), at least 96 (claim 5), or at least 1000 elements (claims 6-8), and that experimental results are provided to the user within 50 (claim 6), 20 (claims 4 and 7) or 10 days (claims 5 and 8) from preparation of the first library.

These claims are rejected based on a combination of Nova, Li, and Falb. Nova is cited for its alleged disclosure of the limitations of claim 1. Li is cited for the alleged disclosure of experiment matrices including at least 50, at least 96, or 127 or more elements and of a variable amount of time before experimental results are available”. *See, e.g.*, Office action at page 26, lines 8-10. Falb is cited for the alleged disclosure of providing experimental results to a user within 10, 20 or 50 days. *See* Office action at page 26, lines 11-14; page 28, lines 16-19; page 30, line 22-page 31, line 3.

As noted above, however, Nova fails to disclose or even suggest at least the provision of experiment design software to a user at a first location and the receipt and execution at a second location of an experiment design generated using such software, which claim 1 requires, or the generation of an experiment design that meets the limitations of that claim. The Office action does not contend that either Li or Falb discloses or suggests these features. Because the cited combination thus fails to disclose or suggest at least these features of the claims, the applicant submits that no *prima facie* showing of obviousness has been established. Claims 4-8 should therefore be allowed.

b. Claims 22-23

Claims 22 and 23 are dependent claims based directly or indirectly on claim 1. In addition to the limitations of that claim, claim 22 recites that the computer-implemented

experiment design tool is configured to enable the remote user to generate an experiment request for execution of the set of experiments defined by the first experiment design for submission over a computer network, where the experiment request includes electronic data embodying the first experiment design. Claim 23 depends from claim 22 and provides that the first experiment design is received from the remote user over a computer network.

These claims are rejected based on a combination of Nova and Lennon. Nova is cited for its alleged disclosure of the limitations of claim 1. Lennon is cited for its alleged disclosure of the generation and submission of experiment requests over a computer network.

As noted above, however, Nova fails to disclose or even suggest at least the provision of experiment design software to a remote user at a first location and the receipt and execution at a second location of an experiment design generated using such software, which claim 1 requires, or the generation of an experiment design that meets the limitations of that claim. Lennon also fails to disclose or suggest at least these features of claim 1.

As its title suggests, Lennon discloses the use of a distributed network of mini-computers to automate a biochemical laboratory. Lennon's stated goal is "to automate an integrated laboratory", which it proposes to do by automating three traditional laboratory roles – those of Chemist, Technician, and Instrument Operator. *See* Lennon, page 156, Introduction, paragraphs 1 & 3. Thus, and is borne out in Lennon's subsequent discussion, Lennon focuses on the tasks of automating and integrating instruments and processes *within* a laboratory. Lennon does not disclose or even suggest the *separation* of experiment design and execution as is contemplated by the present claims, with the latter being performed at the laboratory facilities and the former by users of laboratory services who are remote from the laboratory. Nor does Lennon disclose or suggest the generation of the particular experiment designs recited in claim 1.

Because the cited combination thus fails to disclose or suggest at least these features of the claims, the applicant submits that no *prima facie* showing of obviousness has been established. Claims 22 and 23 should therefore be allowed.

c. Claims 25 & 28

Claims 25 and 28 are dependent claims based directly or indirectly on claim 1. In addition to the limitations of that claim, claim 25 recites that the first experiment design defines a set of experiments directed to chemicatalysis or biocatalysis. Claim 28 recites that the first experiment design defines a set of experiments directed to optimization of a chemical synthetic process (from claim 26) and that the set of experiments is directed to the preparation of fine chemicals.

These claims are rejected based on a combination of Nova and Allen. Nova is cited for its alleged disclosure of the limitations of claim 1. Allen is cited for its alleged disclosure of experiments directed to chemicatalysis or biocatalysis (for claim 25) and fine chemicals (for claim 28).

As noted above, however, Nova fails to disclose or even suggest at least the provision of experiment design software to a user at a first location and the receipt and execution at a second location of an experiment design generated using such software, which claim 1 requires, or the generation of an experiment design that meets the limitations of that claim. The Office action does not contend that Allen discloses or suggests these features. Because the cited combination thus fails to disclose or suggest at least these features of the claims, the applicant submits that no *prima facie* showing of obviousness has been established. Claims 25 and 28 should therefore be allowed.

d. Claim 30

Claim 30 is a dependent claim based on claim 1 and claim 26. In addition to the limitations of those claims, claim 30 recites that the set of experiments is directed to the preparation of commodity chemicals.

Claim 30 is rejected based on a combination of Nova and Chen. Nova is cited for its alleged disclosure of the limitations of claim 1. Chen is cited for its alleged disclosure of experiments directed to the preparation of commodity chemicals.

As noted above, however, Nova fails to disclose or even suggest at least the provision of experiment design software to a user at a first location and the receipt and execution at a second location of an experiment design generated using such software, which claim 1 requires, or the generation of an experiment design that meets the limitations of that claim. The Office action does not contend that Chen discloses or suggests these features. Because the cited combination thus fails to disclose or suggest at

least these features of the claims, the applicant submits that no *prima facie* showing of obviousness has been established. Claim 30 should therefore be allowed.

e. **Claim 46**

As amended, claim 46 is a dependent claim based on claim 39. In addition to the limitations of that claim, claim 46 recites that the experiment design is communicated to the laboratory over a computer network.

Claim 46 is rejected based on a combination of Nova and Lennon. Nova is cited for its alleged disclosure of the limitations of claim 1. Lennon is apparently cited for its alleged disclosure of the communication of experiment designs over a computer network.

As noted above, however, Nova fails to disclose or even suggest at least the generation of an experiment design by a remote user at a first location, the communication of such an experiment design to a laboratory at a second, different location for execution, and the receipt at the first location of experimental results obtained by execution of the experiment design at the laboratory, as claim 39 requires, or the generation of an experiment design that meets the limitations of that claim. Lennon also fails to disclose or suggest at least these features of claim 39.

As its title suggests, Lennon discloses the use of a distributed network of mini-computers to automate a biochemical laboratory. Lennon's stated goal is "to automate an integrated laboratory", which it proposes to do by automating three traditional laboratory roles – those of Chemist, Technician, and Instrument Operator. See Lennon, page 156, Introduction, paragraphs 1 & 3. Thus, and is borne out in Lennon's subsequent discussion, Lennon focuses on the tasks of automating and integrating instruments and processes *within* a laboratory. Lennon does not disclose or even suggest the *separation* of experiment design and execution as is contemplated by the present claims, with the latter being performed at the laboratory facilities and the former by users of laboratory services who are remote from the laboratory. Nor does Lennon disclose or suggest the generation of the particular experiment designs recited in claim 39.

Because the cited combination thus fails to disclose or suggest at least these features of the claim, the applicant submits that no *prima facie* showing of obviousness has been established. Claim 46 should therefore be allowed.

7. New Claims 53-83

New claims 53-58 are dependent claims based on claim 39, and are directed to computer-implemented methods for obtaining experimental results that are directly analogous to dependent claims based on claim 1 that are discussed above. Claims 59-70 are dependent claims based on claim 51, and are directed to computer-readable storage media that include instructions for performing method steps analogous to those recited in claim 1 and its dependent claims. Claim 71 is an independent claim directed to a computer-readable storage medium that includes instructions for performing method steps analogous to those recited in claim 39, and claims 72-83 are dependent claims based directly or indirectly on claim 71 that are directed to computer-readable storage media that include instructions for performing method steps analogous to those recited in claim 39 and its dependent claims. The applicant submits that these claims are allowable over the cited art for at least the reasons discussed above.

8. Conclusion

The applicant submits that all claims are now in condition for allowance. Applicant is paying the filing fees based on the as-amended claims pursuant to the transmittal documents submitted herewith. If necessary, the Examiner is hereby authorized to charge any fees required in connection with this application, throughout the pendency thereof, to Deposit Account No. 50-0496.

Respectfully submitted,

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